IN VIVO EVALUATION OF PRESSURE HEAD AND FLOW RATE ESTIMATION IN A CONTINUOUS-FLOW ARTIFICIAL HEART

A. Tanaka[1], M. Yoshizawa[2], T. Yamada[1], K. Abe[1], H. Takeda[3], T. Yambe[4], S. Nitta[4]
[1]Graduate School of Engineering, Tohoku University, Sendai 980-8579, Japan
[2]Information Synergy Center, Tohoku University, Sendai 980-8579, Japan
[3]Faculty of Engineering, Tohoku Gakuin University, Sendai 985-8537, Japan
[4]Institute of Development, Aging and Cancer, Tohoku University, Sendai 980-8575, Japan

Abstract-**To avoid using sensors with low biocompatibility and low durability in implantable TAH systems, the authors previously proposed a new method for estimating instantaneous values of flow rate and pressure head on the basis of voltage, current and rotational speed in a motor driven centrifugal pump. The previous *in vitro* experiments showed that the proposed estimator could automatically compensate for the effect of the change in blood viscosity on the estimation accuracy by employing two kinds of auto-regressive exogenous model. In this study, validity and reliability of this estimation method were ascertained in an acute animal experiment. In the experiment, two centrifugal blood pumps were implanted into an adult goat as a total artificial heart. Results of estimation were compared with true values when blood viscosity was changed by injecting physiological saline. The results indicated that the system could successfully estimate pressure head by compensating the change of viscosity although the estimation accuracy of the *in vivo* estimation was not so high as that of the previous *in vitro* tests.**

***Keywords* - artificial heart, ARX model, pressure estimation, flow estimation, continuous-flow blood pump**

I. INTRODUCTION

For automatic control of an implantable artificial heart, it is desirable to estimate blood flow and pressure without any sensors implanted inside the recipient's body. In the case of an electric motor driven artificial heart, voltage, current and rotational speed of the motor can be measured easily and accurately. These three signals are closely related to flow of the blood pump and pressure difference (pressure head) between inlet and outlet ports, and then, it is possible to estimate flow and pressure head by processing these signals.

Such an approach has already succeeded to some extent in the case of centrifugal blood pumps in other studies [1-6]. These estimation methods must include compensation procedure for the change in blood viscosity. However, conventional compensation procedures are not suitable for automatic and on-line estimation. For example, hematocrit value may be useful to compensate for the change in blood viscosity [4-6]. However, direct measurement of this value should be avoided because of necessity of another measurement apparatus outside the body.

Previously, the authors proposed a new method for estimating instantaneous values of flow and pressure head on the basis of voltage, current and rotational speed in a DC-motor driven centrifugal pump. The proposed estimator can automatically compensate for the effect of the change in blood viscosity on the estimation accuracy by employing two kinds of auto-regressive exogenous model (ARX model)[7].

In this study, validity and reliability of this estimation method were ascertained in an acute animal experiment. In the experiment, two centrifugal blood pumps were implanted into an adult goat as a total artificial heart. Results of estimation were compared with true values when viscosity of blood had been changed by injecting physiological saline.

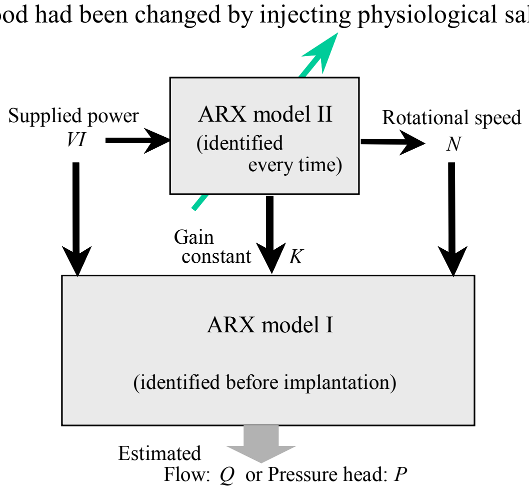

Fig. 1. Block diagram of the proposed estimation system.

II. METHODS

Estimation of Flow Rate and Pressure Head

For general expression, let $y(t)$ denote either pressure head $P(t)$ [mmHg] or flow rate $Q(t)$ [L/min]. Define electrical power $VI(t)$ [W] supplied to the motor as the product of voltage and current. In the steady state or the static situation where the notation of time "(t)" of every variable is omitted, the previous preliminary experiments showed that y can be approximated by

$$y = b_1 N^2 VI + b_2 N\, VI + b_3 VI + b_4 N^2 + b_5 N + b_6 \qquad (1)$$

where b_j; j=1,2,…,6 are constant coefficients.

To estimate the transient response of flow rate or pressure head, the static system (1) should be extended to the following ARX model (*ARX model I*) shown in the lower block in Fig.1 as a dynamic time series model.

$$y(k) + \sum_{i=1}^{L} a_i y(k-i) = \sum_{j=1}^{7} \sum_{1}^{M_j} b_{ij} u_j (k-i) + w(k) \qquad (2)$$

Report Documentation Page

Report Date	Report Type	Dates Covered (from... to)
25 Oct 2001	N/A	-

Title and Subtitle In Vivo Evaluation of Pressure Head and Flow Rate Estimation in a Continuous-Flow Artificial Heart	**Contract Number**
	Grant Number
	Program Element Number
Author(s)	**Project Number**
	Task Number
	Work Unit Number
Performing Organization Name(s) and Address(es) Graduate School of Engineering, Tohoku University, Sendai 980-8579, Japan	**Performing Organization Report Number**
Sponsoring/Monitoring Agency Name(s) and Address(es) US Army Research, Development & Standardization Group (UK) PSC 802 Box 15 FPO AE 09499-1500	**Sponsor/Monitor's Acronym(s)**
	Sponsor/Monitor's Report Number(s)
Distribution/Availability Statement Approved for public release, distribution unlimited	
Supplementary Notes Papers from 23rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society, October 25-28, 2001, held in Istanbul, Turkey. See also ADM001351 for entire conference on cd-rom., The original document contains color images.	
Abstract	
Subject Terms	
Report Classification unclassified	**Classification of this page** unclassified
Classification of Abstract unclassified	**Limitation of Abstract** UU
Number of Pages 4	

where k: the discrete time satisfying $t=k\Delta t$, Δt: the sampling period, $w(k)$: the residue assumed to be a white noise, L: the order of the output, M_j: the order of the input, $u_j(k)$: the following six kinds of exogenous input corresponding to each term of the right hand side of (1) and the additional input K which will be explained later:

$$u_1(k) = N^2(k) \cdot VI(k) \quad (3)$$

$$u_2(k) = N(k) \cdot VI(k) \quad (4)$$

$$u_3(k) = VI(k) \quad (5)$$

$$u_4(k) = N^2(k) \quad (6)$$

$$u_5(k) = N(k) \quad (7)$$

$$u_6(k) = 1 \quad (8)$$

$$u_7(k) = K \text{ (additional input supplied by ARX model II)} \quad (9)$$

Let $M_6 = M_7 = 1$ and $M_1 = M_2 = \cdots = M_5 = M$ for simplicity.

Before implantation of an artificial heart, we can collect the measured data $y(k)$ and $u_j(k)$. Thus, the coefficient parameters a_i and b_{ij} included in (2) can be identified by off-line least squares method on the basis of $y(k)$ and $u_j(k)$. After the identification of a_i and b_{ij}, the ARX model I without $w(k)$ can generate an estimate $\hat{y}(k)$ of $y(k)$ on the basis of on-line measurement of $u_j(k)$.

If blood viscosity considerably changes, the accuracy of the estimation of the ARX model I will decrease because the true coefficients a_i and b_{ij} will also change. Thus, as shown in the upper block in Fig.1, introduce a new ARX model (*ARX model II*) representing a system from power $VI(k)$ to rotational speed $N(k)$ as follows:

$$N(k) + c_1 N(k-1) + c_2 N(k-2) = d_1 VI(k) + d_2 VI(k-1) + d_3 \quad (10)$$

The system (10) yields the steady state gain K as follows:

$$K = \frac{d_1 + d_2}{1 + c_1 + c_2} \quad (11)$$

This parameter K expresses rotational speed per unit time and includes information on the reciprocal of viscosity, and then, K can be used as the additional input $u_7(k)$ given by (9). Moreover, because $VI(k)$ and $N(k)$ can be obtained even after implantation, K can be calculated at any time.

In general, the final prediction error (FPE) or the Akaike's information criterion (AIC) is frequently used to determine the orders (L and M) of ARX models. In this case, however, it has already been ascertained that the determination based on such a criterion tends to yield extremely high orders. A system model with too high orders is apt to produce large estimation error even if the true system slightly changes from the original identified situation. Thus, the number L and M can be chosen under 20 so as to minimize the root mean square value e of the error between $y(k)$ and its estimate $\hat{y}(k)$ defined as

$$e = \sqrt{\frac{1}{K_D} \sum_{k=1}^{K_D} \{y(k) - \hat{y}(k)\}^2} \quad (12)$$

where K_D is the size of data.

Acute Animal Experiment

In order to evaluate the estimation system, an acute animal experiment was executed using an adult goat. Two centrifugal pumps (Terumo Co. Ltd; CAPIOX) for right and left hearts were installed as the biventricular bypass. Right and left inflow cannulae were inserted into the left and right atriums, respectively. Left and right outflow cannulae were sutured on the descending aorta and the pulmonary artery, respectively. Aortic pressure (*AoP*) and pulmonary arterial pressure (*PAP*) were measured using pressure transducers at the outlet port of the left and right pumps, respectively. Left and right atrial pressures (*LAP*, *RAP*) were measured at the intake ports of the left and right pumps, respectively. Left and right pump flow rate (Q_L, Q_R) were measured with electromagnetic flowmeters. Rotational speed of each motor was stored in a personal computer through the serial communication port with each pump driver. All the measurements were stored at 5Hz in a personal computer.

The driving voltage of the left pump was changed manually according to a step-like signal in order to maintain the condition of the persistent excitation [8] for accurate identification. The right pump was controlled automatically so that *LAP* may approach *RAP* to keep the perfusion balance between systemic and pulmonary circulation. Blood viscosity was changed at several times by intravenous infusion of physiological saline.

In this study, P_L=*AoP*–*RAP* and Q_L were estimated off-line by using a self-produced software based on MATLAB (Mathworks Inc.)

III. RESULTS

To evaluate the effect of the compensation procedure for change in blood viscosity of the proposed method, this method was compared with another method without compensation ability. The compared method has only the ARX model I given by (2) without the additional input $u_7(k)=K$.

First, measured $P(k)$, $Q(k)$, $VI(k)$ and $N(k)$ were stored every Δt = 200ms for 600s. The data were divided into four segments by tree beginning points of infusion. The ARX model II was identified by the off-line least square method in each segment, and then K was calculated in the four segments. Both ARX models I with and without K were also identified by the off-line least squares method. In the estimation of flow rate and pressure head, the same input data as used in the identification was supplied to the models

Fig. 2 shows the result of estimation of the pressure head P_L of the left pump obtained from the ARX model I without K. Each vertical line shows the time when physiological saline was injected. In this figure and also the other figures which will be shown later, it can be seen that the proposed system could not estimate relatively high frequency component (near the frequency of heart beat) included in the true value. An underestimation can be observed after the first infusion. The estimation error e defined by (12) and correlation coefficient between $y(k)$ and $\hat{y}(k)$ were 7.44mmHg and 0.724, respectively.

Fig. 3 also shows the result of estimation of P_L obtained from the combination of the ARX model I with $u_7(k)=K$ given by (2) and the ARX model II given by (10). It can be observed that the error of estimation was slightly reduced from that shown in Fig.2. This may be because the effect of the change in blood viscosity was compensated by K. The mean value of estimation error and correlation coefficient were 6.77 mmHg and 0.775, respectively.

Fig. 4 and 5 show the results of estimation of flow rate Q_L based on the ARX model I without K and the ARX models I and II including K, respectively. It is shown that both estimates were almost the same as each other. In both figures, the estimation error and correlation coefficient were 0.27L/min and 0.875, respectively. This means that the effect of introduction of K on improvement in estimation accuracy was hardly observed in the case of estimation of flow rate although K was actually different in each interval.

The above four results of estimation are put together in Table I.

TABLE I
ESTIMATION ERROR AND CORRELATION COEFFICIENT

		Estimation error e	Correlation coefficient
Estimation of pressure head	Without K	7.39 mmHg	0.724
	With K	6.77 mmHg	0.775
Estimation of flow rate	Without K	0.27 L/min	0.875
	With K	0.27 L/min	0.875

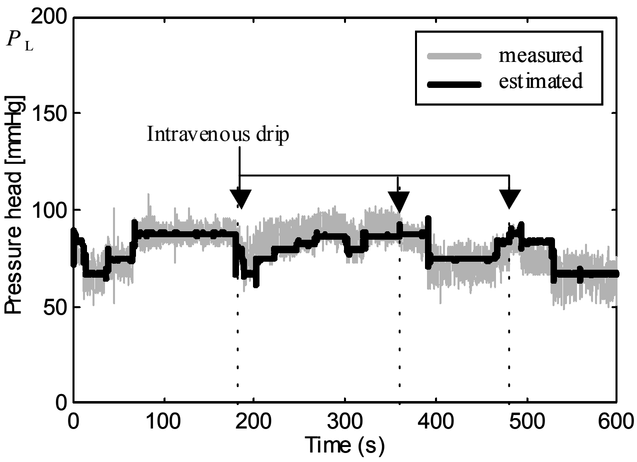

Fig. 2. Estimation of pressure head based on (2) without K.

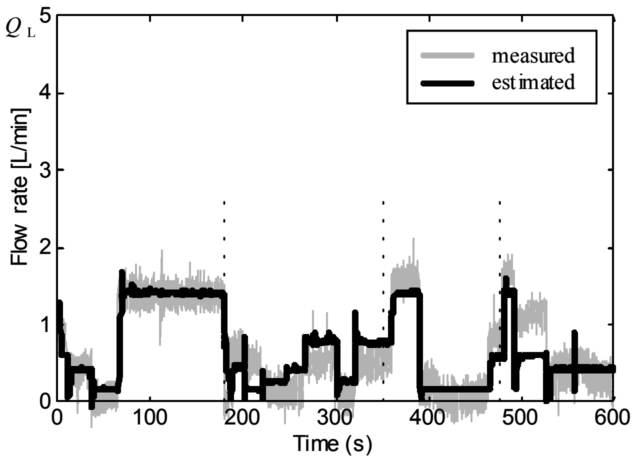

Fig. 4. Estimation of flow rate based on (2) without K.

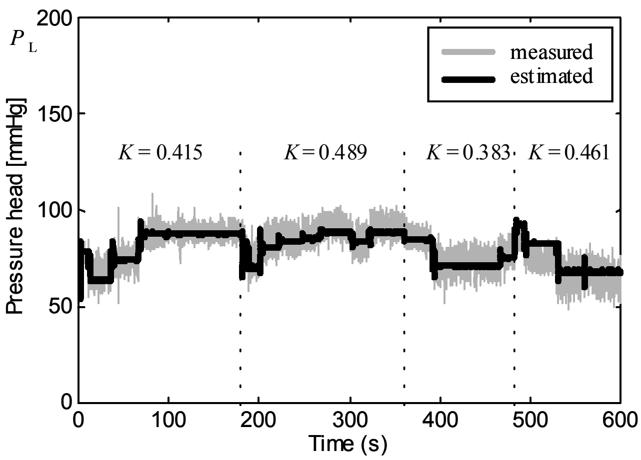

Fig. 3. Estimation of pressure head based on (2) with K.

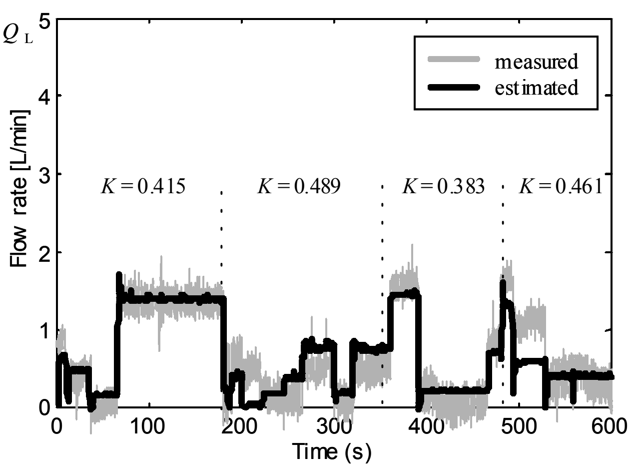

Fig. 5. Estimation of flow rate based on (2) with K.

IV. DISCUSSION

In the case of estimation of pressure head, the effect of the additional input, i.e., the gain constant K on depression of estimation error could be verified. However, this effect was not so large than we had expected on the basis of the previous *in vitro* results [7] obtained from a mock circulatory system. This may be because the change in blood viscosity caused by infusion of physiological saline was not so sufficient as that can be realized in the mock circulatory system.

On the other hand, in the case of flow rate, the improvement in the estimation accuracy could not be observed by the introduction of K. This may be because the magnitude of flow rate was too small to cause on acute identification.

As shown Table I, the estimation accuracy in the animal experiment was not high in comparison with the result *in vitro* [7]. This may be because the beating components of the natural heart were included in the data of P_L and Q_L.

One of the most important problems in this estimation method is when and how the coefficient parameters of the ARX model I should be estimated because the ARX model I cannot, of course, be identified when the true values of $P(t)$ and $Q(t)$ cannot be measured. It is desirable that the parameters can be identified using the data obtained from *in vitro* experiments. In this case, however, it is considerably sure that the identified values of the parameters will become different from the true values in an actual *in vivo* situation after implantation of the TAH. Therefore, the identification should be carried out while the operation of the TAH implantation by using flow and pressure sensors equipped temporally. In this case, however, it is necessary to change the gain constant K or blood viscosity for accurate identification in spite of difficulty.

Kitamura et al. [9] also proposed the estimation method of pressure head and flow rate using motor current and rotation speed. This method can compensate the effect of blood viscosity because the viscosity is also estimated in an online and real-time fashion by using motor current and rotation speed. However, this method has not yet obtained enough accuracy and robustness in animal experiments

V. CONCLUSION

In this study, in order to ascertain the adequacy of the estimation method proposed in the authors' previous study, an acute animal experiment was carried out using an adult goat equipped with a TAH consisting of two centrifugal pumps. The results showed that the ARX model with an additional input, i.e., the gain constant of the system from electrical power to rotational speed of the motor could compensate for the change in blood viscosity. However, the estimation accuracy of the *in vivo* estimation was not so high as that of the previous *in vitro* tests.

In further studies, it is necessary for clinical use to investigate the effect of changes in environmental situations except viscosity and individual differences on the model parameters. To improve the estimation accuracy, it can be also considered that artificial neural networks [10] should be introduced to the estimator to compensate the nonlinear part of the residue which cannot be expressed by linear models such as ARX models.

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